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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,376	05/02/2006	Claus Harder	117163.00158	8059

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EXAMINER	
GANESAN, SUBA	

ART UNIT	PAPER NUMBER
3774	

NOTIFICATION DATE	DELIVERY MODE
06/20/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@hahnlaw.com
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Office Action Summary	Application No.	Applicant(s)	
	10/562,376	HARDER ET AL.	
	Examiner	Art Unit	
	SUBA GANESAN	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4 and 15-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4 and 15-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/15/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1-2, 4, and 15-17have been considered but are moot in view of the new ground(s) of rejection.

2. Applicant has amended claim 1 to include reference to a third pharmaceutical and an elution profile that describes Applicant's fig. 5. Sirhan teaches the addition of additional therapeutic agent onto the stent (para 121 and 122, see rejection, infra). Additionally, Herweck teaches the desirability of adding additional therapeutic material to a portion of the device resulting in more therapeutic agent available without compromising the flexibility of the stent.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-2, 4, 15 and 22-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1 line 16-17, the claim recites "wherein the second polymer carrier exhibits a more rapid degradation behavior than the first polymer carrier." This limitation is considered indefinite because it lacks antecedent basis in the claim, insofar as claim 1 does not specify that the first polymer carrier is degradable. The claim scope is thus unclear as to whether the first polymer carrier must be degradable.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims **1-2**, **4** and **15-24** are rejected under 35 U.S.C. 102(e) as being anticipated by Sirhan et al. (Pub. No.: US 2003/0083646) in view of Johnson (U.S. Pat. No.: 5,972,027), further in view of Herweck et al. (U.S. Pat. No.: 2003/0153901).

2. Sirhan et al. (hereafter, Sirhan) discloses a stent with a coating system (para. 18, 20) comprising one or more polymer carriers (para. 25, 26, 27) and at least a first and second pharmaceutically active substance (para. 17, 56, 58 and 59) dispersed in the first polymer carrier (para. 56: the first and second therapeutic capable agents may be released from the same layer). The elution of the pharmaceutically active substances varies in the longitudinal direction of the stent (para 34: "areas (e.g., distal and proximal ends of the device) having variable thickness of both the source and the rate-controlling element to allow for slower or faster release," also see para 135).

3. However, Sirhan lacks a concentration of drug greater adjacent the face surfaces that the middle with a second drug with a greater concentration in the middle than the face surfaces. Johnson teaches the use a release profile of multiple drugs with different concentrations based on the porosity of the stent (see fig. 5 and col. 4 lines 33-50) for the purpose of treating restenosis with multiple drugs. It would have been obvious to

one of ordinary skill in the art at the time the invention was made to have provided the coated stent with variable drug concentration in the coating as disclosed by Sirhan with the release profile as taught by Johnson such that a first drug has a higher concentration at the ends of the stent and a second drug has a higher concentration in the middle of the stent, for the purpose of treating restenosis with multiple therapeutic agents.

4. The combination of Sirhan teaches the additional deposition of a pharmaceutical on portions of the stent device (para. 121: "additionally the therapeutic capable agent may be present in smaller surface areas"). This is considered a third pharmaceutically active substance integrated into a second polymer carrier. The second polymer carrier exhibits a more rapid degradation behavior than the first polymer carrier (para. 122: "each source . . . may make the therapeutic capable agent available to the susceptible tissue site at same or different phases and/or rates". Additionally, Herweck et al. (hereafter, Herweck) teach the addition of a drug delivery panel onto the surface of an implantable medical device for the purpose of providing a kinetic release of the agent at a desired location within a body lumen, suggesting that it is known in the art to provide an additional means of therapeutic agent delivery. Herweck teaches the use of the panel in the mid portion of a stent as a means of providing a higher volume of kinetic drug release potential without increasing the thickness of any surface coating (para. 18). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the combination of Sirhan and Johnson with a third pharmaceutically active substance and a second polymer carrier as taught by

Sirhan and Herweck in order to add more drug to the stent. One of ordinary skill in the art would be motivated to add a third pharmaceutical for the purpose of delivering a drug-dosage cocktail specifically tailored to a patient's needs.

5. The polymer carrier is biodegradable (para 36). The degradation behavior of the carrier serves to differentiate the local elution characteristic (para 40, 45-46, for example). The concentration of the pharmaceutically active substances is greater adjacent the face surfaces than in a middle portion of the stent (para 34). The concentration of pharmaceutically active substance is essentially the same in both the first and second polymer carriers.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUBA GANESAN whose telephone number is (571)272-3243. The examiner can normally be reached on M-F 7-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DAVID ISABELLA/
Supervisory Patent Examiner, Art Unit 3774

/S. G./
Examiner, Art Unit 3774